

73049-477

05/03/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 03 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Doina Bujor
Regulatory Manager
Valent BioSciences, Inc.
870 Technology Way
Libertyville, IL 60048

Subject: Product Name: *Bacillus thuringiensis* subsp. *israelensis* Slurry
EPA Reg. No.: 73049-477
Application for Notification Dated: April 4, 2013

Dear Ms. Bujor:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10, and it has been determined that the action requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification accepted" and placed accordingly in our records.

Questions concerning this action should be directed to Michael Glikes at (703)305-6231 or glikes.michael@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kim Nesci", is written over a horizontal line.

Kimberly Nesci, Chief
Microbial Pesticides Branch
Biopesticides & Pollution Prevention Division



United States
Environmental Protection Agency
Washington, DC 20460

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Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73049-477	2. EPA Product Manager Sheryl Reilly	3. Proposed Classification ☒ None ☐ Restricted
4. Company/Product (Name) Bacillus thuringiensis subsp. israelensis Slurry	PM# 92	
5. Name and Address of Applicant (Include ZIP Code) Valent BioSciences Corporation 870 Technology Way Libertyville, IL 60048 ☐ Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

☐ Amendment - Explain below.	☒ Final printed labels in response to Agency letter dated August 10, 2011
☐ Resubmission in response to Agency letter dated _____	☐ "Me Too" Application.
☐ Notification - Explain below.	☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final printed label

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging ☐ Yes ☒ No	Unit Packaging ☐ Yes ☒ No	Water Soluble Packaging ☐ Yes ☒ No	☒ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information ☒ Label ☐ Container		4. Size(s) Retail Container		5. Location of Label Directions ☒ On Label ☐ On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled		☐ Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Doina Bujor	Title Regulatory Manager	Telephone No. (Include Area Code) 847-968-4724
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Manager	
4. Typed Name Dona Bujor	5. Date Apr 4, 2013	

Bacillus thuringiensis subsp. israelensis Slurry

(for liquid VectoBac formulations)

BIOLOGICAL INSECTICIDE

FOR MANUFACTURING USE ONLY

KEEP OUT OF REACH OF CHILDREN
CAUTION

Notification Accepted

Date: May 3, 2013

Reviewer: GIKes

ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. *israelensis*, strain AM 65-52 solids, spores and insecticidal toxins

OTHER INGREDIENTS:

Total: 14.0% w/w

The % active ingredient does not indicate product performance

86.0% w/w

100% w/w

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

FIRST AID

- If in eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
 - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
 - Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, you may also call toll-free 1-877-315-9819 for treatment information.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. This slurry is intended for formulation into insecticidal products for control of mosquito larvae.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in cool, dry conditions.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on-site or at an approved waste disposal facility.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

Registrant/Manufactured for:
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048
1-800-323-9597

Manufactured by:
AbbVie Inc.
1401 Sheridan Road
North Chicago, IL 60064

EPA Registration No. 73049-477
EPA Est. No. 275-IL-001
Code No. 59304
Net Contents: Bulk (Tank Truck)

List No. 10604

Lot No.